MAY 0 9 2002

K020724

Summary of Safety and Effectiveness Information

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Submitter's Name: Richard M. Vaught
Dade Behring Inc.
P.O. Box 6101
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Date of Preparation: March 5, 2002

Name of Product: Dade Behring Dimension® Automated LDL Cholesterol Flex® reagent cartridge method

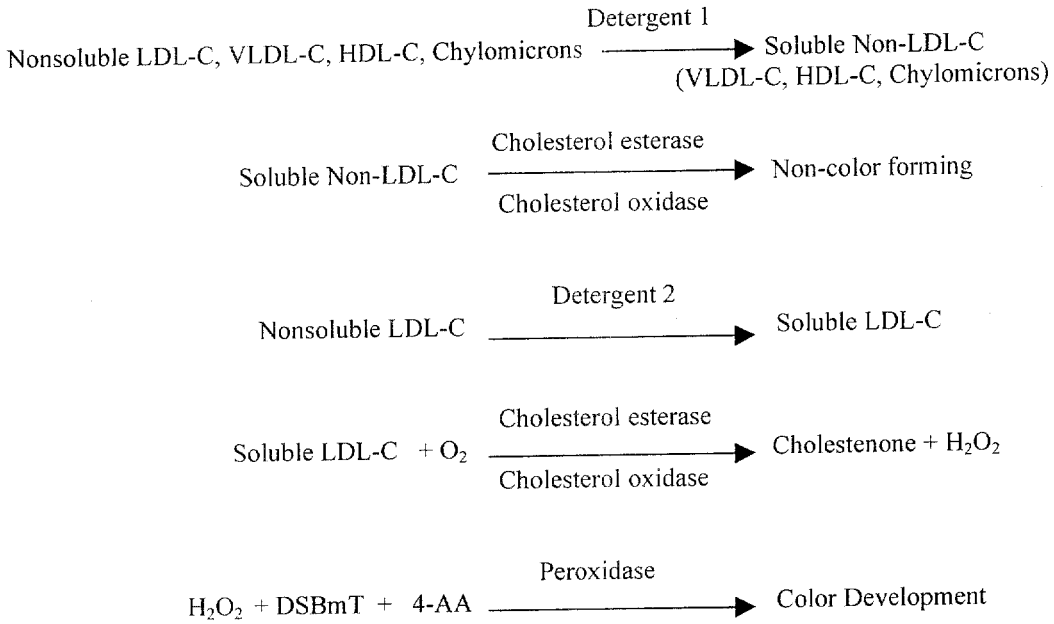
FDA Classification Name: Lipoprotein test system

Predicate Device: The Genzyme N-geneous™ LDL-Cholesterol assay (K971573) and the Beta-Quantification reference method utilized by the Cholesterol Reference Method Laboratory Network (CRMLN).

Device Description: The Dade Behring Dimension® Automated LDL Cholesterol Flex® reagent cartridge method is an *in vitro* diagnostic test that consists of prepackaged reagents in a flexible plastic cartridge for use on the Dimension® clinical chemistry system. The Dimension® Automated LDL Cholesterol Flex® reagent cartridge assay is a homogeneous method for directly measuring low-density lipoprotein cholesterol in human serum or plasma without the need for off-line pretreatment or centrifugation steps.

The method is in a two reagent format and depends on the properties of detergent 1 which solubilizes only non- LDL particles. The cholesterol released is consumed by cholesterol esterase and cholesterol oxidase in a non-color forming reaction. Detergent 2 solubilizes the remaining LDL particles. The soluble LDL-C is then oxidized by the action of cholesterol esterase and cholesterol oxidase forming cholestenone and hydrogen peroxide

(H_2O_2). The enzymatic action of peroxidase on H_2O_2 produces color in the presence of N,N-bis(4-sulfobutyl)-m-toluidine, disodium salt (DSBmT) and 4-aminoantipyrine (4-AA) that is measured using a bichromatic (540 nm, 700 nm) endpoint technique. The color produced is directly proportional to the amount of LDL-C present in the sample.



Intended Use: The Dimension® Automated LDL Cholesterol Flex® reagent cartridge method is an *in vitro* diagnostic test intended for the quantitative determination of low-density lipoprotein cholesterol in human serum and plasma.

Comparison to Predicate Device: A summary of features for the Dimension® Automated LDL Cholesterol Flex® reagent cartridge method and the predicate device, the Genzyme N-geneous™ LDL Cholesterol reagent set (K971573) as utilized on automated analyzers are provided in the following chart:

	Dade Behring Dimension® Automated LDL Cholesterol Flex® reagent method	**Genzyme N-geneous™ LDL Cholesterol assay (for use on automated analyzers)**
Intended Use	*in vitro* use	*in vitro* use
Sample size	3 uL	3 uL
Measurement	Direct LDL determination; Bichromatic endpoint; 540 nm and 700nm	Direct LDL determination; Bichromatic endpoint; 546 nm and 660 nm
Reagents	Two-detergent Genzyme N-geneous™ LDL Cholesterol reagent set	Two-detergent Genzyme N-geneous™ LDL Cholesterol reagent set

Additionally, comparative performance studies were conducted between the Dimension® Automated LDL Cholesterol Flex® reagent cartridge method and both the Genzyme N-geneous™ LDL Cholesterol assay (on the Beckman CX-9 automated analyzer) and the CRMLN Beta-Quantification reference method. The results are summarized below:

Comparative Method	Slope	Intercept (mg/dL) [mmol/L]	Correlation Coefficient	n
Genzyme N-geneous™ LDL Cholesterol assay	0.95	4.7 [0.12]	0.997	122
Beta-Quantification method	1.01	3.3 [0.08]	0.982	49

Comments on Substantial Equivalence: The Dimension® Automated LDL Cholesterol Flex® reagent cartridge method has the same intended use, employs the same design, and utililzes the same reagent set as the predicate device, the Genzyme N-geneous™ LDL Cholesterol reagent set (K971573).

Conclusion: The Dimension® Automated LDL Cholesterol Flex® reagent cartridge method is substantially equivalent in design and performance to both the Genzyme N-geneous LDL Cholesterol assay and the CRMLN Beta-Quantification reference method based on the comparison studies as described above.

Richard M. Vaught
Regulatory Affairs and Compliance Manager
March 5, 2002

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAY 0 9 2002

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Regulatory Affairs and Compliance Manager
Dade Behring Inc.
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Re: k020724
Trade/Device Name: Dimension® Automated LDL Cholesterol Flex® Reagent Cartridge Method
Regulation Number: 21 CFR 862.1475
Regulation Name: Lipoprotein test system
Regulatory Class: Class I, reserved
Product Code: MRR
Dated: March 5, 2002
Received: March 6, 2002

Dear Mr. Vaught:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory-Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications For Use Statement

K020724

Device Name:

Dimension® Automated LDL Cholesterol Flex® reagent cartridge method

Indications for Use:

The Dade Behring Dimension® Automated LDL Cholesterol Flex® reagent cartridge method is an *in vitro* diagnostic test intended for the quantitative determination of low-density lipoprotein cholesterol in human serum and plasma. Lipoprotein measurements are used in the diagnosis and treatment of lipid disorders (such as diabetes mellitus), atherosclerosis, and various liver and renal diseases.

Richard M. Vaught
Regulatory Affairs and Compliance Manager

March 5, 2002

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K020724

Prescription Use X **OR** **Over-the-counter Use**_____
(Per 21 CFR 801.109)

(Optional format 1-2-96)